# TECHNICAL FILE

## Arterial Leadercath

5115.098 20.

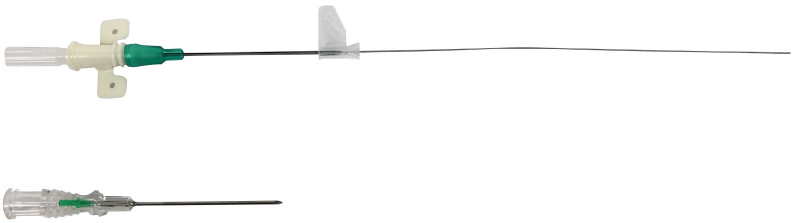
Dated : 22-02-2023

## 1 Administrative information relating to the company

| | | |
|---|---|---|
| 1.1 | **Name** : Vygon | |
| 1.2 | **Address :**<br>5 rue Adeline - 95440 Ecouen, France | **Fax :** + 33 (0)1 34 29 19 34<br>**E-mail :** questions@vygon.com<br>**Website :** www.vygon.com |
| 1.3 | **Medical Device vigilance Representative :**<br>Laurent GUILLARDEAU | **Tel :** +33 (0)1 39 92 65 69<br>**Fax :** +33 (0)1 39 92 64 82<br>**E-mail :** quality@vygon.com |

## 2 Information about the device or equipment

| | |
|---|---|
| 2.1 | **Generic name :** Arterial catheter (Seldinger technique) |
| 2.2 | **Commercial name :** Arterial Leadercath |
| 2.4 | **Medical Device Class :** IIa<br>**Applicable regulation :** 93/42/CEE<br>**in accordance with Appendix n° :** II<br>**Notified body N° :** 0459<br>**Medical Device Manufacturer :** Vygon |
| 2.5 | **Description of the device :**<br>Arterial Leadercath are single lumen polyurethane radio-opaque arterial catheters.<br>These catheters are introduced by a classic Seldinger technique.<br>They are indicated for a short term therapy up to 30 days for new born (>3.5kg), child and adult arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling.<br>Common insertion sites are the radial, brachial, and femoral arteries. Less frequently used insertion sites are the ulnar, axillary, posterior tibial, and dorsal pedis arteries.<br><br>Contents:<br>One radio-opaque catheter (which features an anti-kinking sleeve) and accessories/components to allow its insertion:<br>- One puncture needle,<br>- One straight stainless steel radio-opaque guidewire with one supple extremity,<br>- Codes 5115.094/096/098 feature a centering guidewire introducer, which helps to insert the catheter over the guidewire. |

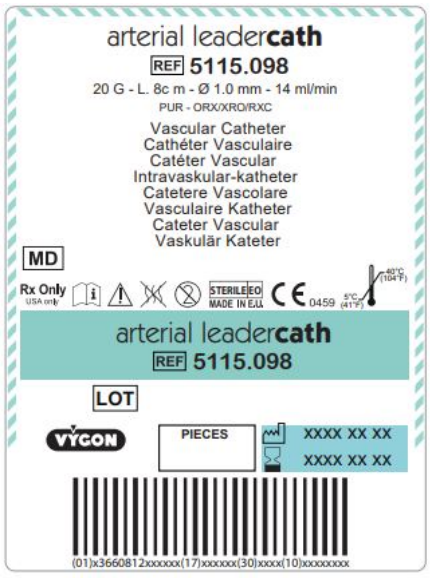


## 2.6 Packaging / Containers

| Code | Single unit packaging | Multi unit packaging | Minimum delivery quantity | Case |
|---|---|---|---|---|
| 5115.098 | 1 (Rigid blister in APET ) | 20 (Carton box) | 20 (Carton box) | 180 (Carton box) |

### Single unit packaging


### Box



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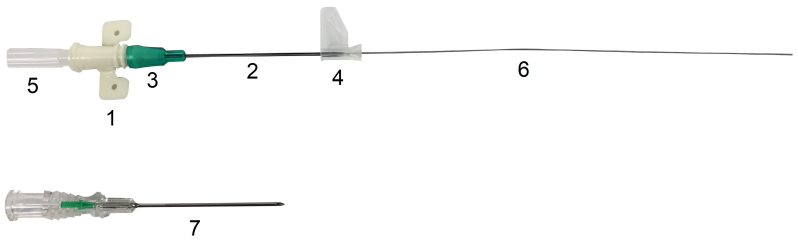
**Technical features :**

| Code | Catheter | | | | | | Puncture needle | | | | Guidewire | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Length cm | Int. Ø mm | Ext. Ø mm | Gauge G | Ø Fr | Flow rate ml/min | Length mm | Int. Ø mm | Ext. Ø mm | G G | Length cm | Ext. Ø mm |
| 5115.098 | 8 | 0.6 | 1.0 | 20 | 3 | 14 | 38 | 0.6 | 0.9 | 20 | 19 | 0.46 |

**2.7 Composition of the device and Accessories :**

| COMPONENTS | MARKER | MATERIALS |
|---|---|---|
| Hub | 1 | PU |
| Catheter | 2 | PU |
| Anti-kinking device | 3 | PVC |
| Guidewire introducer | 4 | EVA |
| Cap | 5 | PE |
| Guidewire | 6 | Stainless steel |
| Puncture needle | 7 | Stainless steel / MABS / PE |




**For components which are likely to come into contact with the patient and/or administered products, additional points :**
Latex-free
DEHP-free
Does not contain any products of animal or biological origin
Pyrogen-free

**2.8 Indications :**
They are indicated for a short term therapy for arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling.

## 3 Accessories

## 4 Sterilization process

| | |
|---|---|
| | **Sterile Medical Device :** YES<br>**Sterilization made for the device :** Ethylene oxide |

## 5 Conditions of conservation and storage

| | |
|---|---|
| **5.1** | **Normal conservation and storage conditions :**<br>Storage environment temperature: between 5 and 40°C. Store protected from moisture and sunlight. |
| **5.2** | **Special precautions :**<br>Please refer to instructions for use included in the packaging. |
| **5.3** | **Duration of product validity :** 60 months |

## 6 Security of use

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|---|---|
| | **Technical security :**<br>Please refer to instructions for use included in the packaging. |

## 7 Instructions for use

| | |
|---|---|
| **7.1** | **Instructions :**<br>Please refer to instructions for use included in the packaging. |
| **7.2** | **Indications :**<br>They are indicated for a short term therapy for arterial catheterization to perform invasive continuous arterial pressure measurement or to allow repeated arterial blood sampling. |
| **7.3** | **Precautions :**<br>Please refer to instructions for use included in the packaging.<br>Re-use of this device may change its mechanical or biological features and may cause device failure, allergic reaction or bacterial infections. |
| **7.4** | **Contra indications :**<br>Please refer to instructions for use included in the packaging. |

## 8 Additional information relating to the product